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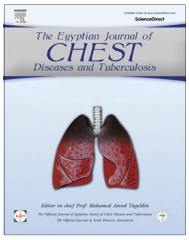

ORIGINAL ARTICLE

Tuberculosis situation in Port Said governorate (1995–2011) before and after Direct Observed Therapy Short Course Strategy (DOTS)

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KEYWORDS

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Abstract *Background:* Tuberculosis (TB) is a major cause of illness and death worldwide, especially in Asia and Africa. In the early 1990s tuberculosis control in Egypt faced many problems. Major progress in global tuberculosis control followed the widespread implementation of the DOTS strategy.

Aim: The objective of this work was to study the tuberculosis situation in Port Said governorate from (1995–2011) before and after Direct Observed Therapy Short Course Strategy (DOTS).

Methods: This was a retrospective clinical cohort study carried out at the Port Said governorate. The registered data about all TB cases over a period of 16 years (1995–2011) before and after the application of DOTS were collected from the chest hospital and TB registration units.

Results: Percentages of cure and complete treatment significantly increased after DOTS (48.7% and 29.3% respectively) than before (19.5% and 13.7% respectively) ($P < 0.001$). On the other hand, failure, death, default and transfer out decreased after DOTS (5.9%, 3.2%, 7.5% and 5.4% respectively) than before it (6.5%, 6.1%, 34.7% and 19.5% respectively), the results were significant ($P < 0.05$) for all of them except treatment failure. The mean values of incidence rates (new and relapse cases, all cases and new smear positive pulmonary TB cases) of TB significantly ($P < 0.05$) decreased after the application of DOTS. Also, the cure rate and treatment success rate significantly increased ($P = 0.001$), while retreatment TB cases rate, default rate, transfer out rate and retreatment failure rate significantly decreased ($P < 0.05$). Finally new pulmonary TB cases with no smear result significantly ($P < 0.05$) increased after DOTS.

Conclusion: The introduction of DOTS in the Port Said governorate has led to a significant increase in the treatment success (82.7%) (Near the WHO target "85%"), and a decrease in the default and failure rates.

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Introduction

Despite the availability of highly efficacious treatment for decades, TB remains a major global health problem. Globally, 9.2 million new cases and 1.7 million deaths from TB occurred in 2006, of which 0.7 million cases and 0.2 million deaths were in HIV-positive people [19].

In the early 1990s tuberculosis control in Egypt faced many problems, the most important of these problems were: Refusal by tuberculous patients to be hospitalized for their treatment, high defaulter rate, increasing levels of resistance against anti-tuberculous drugs and insufficient and deficient health education to both community and health staff [11].

Directly observed therapy short course (DOTS) means that a trained health care worker or other designated individuals provides prescribed anti-tuberculous drugs and watches the patient while swallowing each dose [3]. The main goals of tuberculosis treatment are to cure individual with the disease and minimize the transmission of mycobacterium tuberculosis to others in the community [6]. Major progress in global tuberculosis control followed the widespread implementation of the DOTS strategy. The Stop TB Strategy, launched in 2006, builds upon and enhances the achievements of DOTS. The five components of DOTS are: Sustained government commitment to TB control, case detection through sputum-smear microscopy in the general health services, standardized short-course chemotherapy to all TB cases under proper case management conditions, regular, uninterrupted supply of all essential anti-tuberculosis drugs and monitoring system for program supervision and evaluation [14].

The DOTS strategy has been implemented successfully in many countries and contexts. Through 2003, DOTS has been implemented in 182 of 211 countries, covering 77% of the world's population. In 132 countries, including most of the industrialized world, DOTS is available to more than 90% of their population. Average treatment success among all national DOTS programs is 82%, close to the 85% global target. By 2005, more than 20 million patients have been treated under DOTS, with an expected case detection rate of close to 50%. While the case detection rate has been increasing over the past decade, it is still below the 70% target [18].

A more positively, and reinforcing finding first reported in 2007, is that the number of new cases has been falling globally since 2003. Globally, the rate of case detection for smear positive cases reached 61% in 2006 compared with the target of at least 70%; and the treatment success rate improved to 84.7% in 2005 [19].

A study conducted to assess the cost-effectiveness of DOTS in Egypt, comparing DOTS delivered though primary health care centers (PHCs), chest clinics and chest hospitals with non DOTS. Costs are calculated for both patients and health services. Measurement of effectiveness is the number of patients cured. The study showed that DOTS delivered through PHCs is the most cost effective way of treating TB. The study also found that DOTS delivered through PHCs does not increase the cost to the patient and the lower defaulting rates suggest a reduction in future retreatment costs comparing the alternative treatment options [12].

Aim: The objective of this work was to study the tuberculosis situation in the Port Said governorate from (1995–2011) before and after the application of Direct Observed Therapy Short Course Strategy (DOTS).

Methodology

This was a retrospective clinical cohort study carried out at the Port Said governorate. The registered data about all TB cases over a period of 16 years (1995–2011) were collected from the TB registration units in the Port Said governorate. This period includes 2 stages; two years (1995, 1996) before the application of DOTS and fifteen years (1997–2011) after it.

- **The Collected data included:**
  (1) TB registration code and the year.
  (2) Socio demographic data which included name, age, sex and residence.
  (3) Forms of tuberculosis; either: Pulmonary (either smear positive or smear negative) or extra pulmonary (and its site as LN, intestine, meninges, breast, renal).
  (4) History of previous treatment if present (Category of patients or type of the patient); either new, relapse, treatment after failure, treatment after default, transfer in or others.
  (5) Schedule of treatment (Recommended standardized treatment regimen) according to NTP [13].
  (6) The recorded follow up for smear-positive pulmonary tuberculosis included sputum smear microscopic examination for acid fast bacilli, at the end of the 2nd month, at the end of the 5th month and at the end of treatment [13].
  (7) Outcome: which included: Cure, treatment completed, treatment failure, died, default and transfer out.
  (8) Culture result: The total number of cases examined yearly by culture and its result.
- **TB indicators** designed by The World Health Organization [17] to determine national TB program (NTP) quality and effectiveness were calculated, These indicators are:
  - Incidence rates (case notification rate): For new cases, new and relapse cases, all cases and new smear positive pulmonary cases.
  - New pulmonary TB cases with no smear result.
  - New adult smear positive cases.
  - Re-treatment TB cases.
  - New extra pulmonary TB cases.
  - New TB cases with no smear conversion result.
  - Sputum conversion rate at the end of the initial phase of treatment.
  - Cure rate.
  - Treatment completion rate.
  - Death rate.
  - Treatment failure rate.
  - Default rate.
  - Transfer out rate.
  - Re-treatment failure rate (chronic TB rate).
  - Comparison of indicators before and after DOTS was carried out.

Statistical analysis

The collected data were tabulated and analyzed using SPSS version 16 software, categorical data were presented as number and percentages while continuous variables were presented as

mean and standard deviation. Chi square test, Fisher's exact test and Student "*t*" test were used. Microstat software was used to calculate "*Z*" test for 2 proportions of 2 independent groups. $P < 0.05$ was considered significant.

Results

The majority (67.9%) of the studied patients were between 15 and less than 30 years old. The highest percentage (80.2%) were males and 89.6% were from urban areas Table 1.

There was a statistically significant difference ($P < 0.05$) regarding the socio-demographic characters of patients before and after the application of the program, where, infection among younger ages (15− and 30−) decreased significantly (42.4% and 35.9% before DOTS and 31.4% and 34.4% after DOTS). The percentage of infected males was lower after DOTS than before (79% and 86.3% respectively). Infection among rural residents also became lower after DOTS than before (7.7% and 23.7% respectively) Table 2.

Results showed also that percentage of pulmonary TB was lower after the application of DOTS (84.9%) than before (94.3%). Regarding the smear results at diagnosis, it was 87.8% before DOTS and became 70.9% after. The percentages of smear −ve cases at 2nd, 3rd, and 5th month and end of treatment were higher after DOTS than before (63%, 55%, 62.9% and 54.6% respectively after DOTS and (38.7%, 24.8%, 17.4% and 25.2% respectively before DOTS). All these differences were statistically significant ($P < 0.05$) for all. The table also shows that culture was done for only 2.4% of the studied patients Table 3.

This work found that the relapse significantly ($P < 0.001$) decreased after the application of DOTS. Regarding treatment outcome, it showed that the percentages of cure and complete treatment significantly increased after DOTS (48.7% and 29.3% respectively) than before (19.5% and 13.7% respectively) ($P < 0.001$). On the other hand, failure, death, default and transfer out decreased after DOTS (5.9%, 3.2%, 7.5% and 5.4% respectively) than before DOTS (6.5%, 6.1%, 34.7% and 19.5% respectively), the results were significant ($P < 0.05$) for all of them except treatment failure Table 4.

The mean values of incidence rates (new and relapse cases, all cases and new smear positive pulmonary TB cases) of TB significantly ($P < 0.05$) decreased after the application of DOTS. Also, the cure rate and treatment success rate significantly increased ($P = 0.001$), while retreatment TB cases rate, default rate, transfer out rate and retreatment failure rate significantly decreased ($P < 0.05$). Finally new pulmonary TB cases with no smear result significantly ($P < 0.05$) increased after DOTS Table 5.

Table 1 Socio-demographic characters of the studied sample.

Variable		Total ($N = 1522$)	% (100.0)
Locality	Port-Said	1497	98.4
	Port-Fuad	25	1.6
The studied patients	Before DOTS (1995, 1996)	262	17.2
	After DOTS (1997–2011)	1260	82.8
Age	<15	46	3.0
	15−	507	33.3
	30−	527	34.6
	45−	333	21.9
	60+	109	7.2
Gender	Male	1221	80.2
	Female	301	19.8
Residence	Urban	1363	89.6
	Rural	159	10.4

Discussion

This study investigated the situation of tuberculosis in the Port Said governorate from January 1995 till December 2011, before and after the application of Direct Observed Therapy Short Course Strategy (DOTS). The total number of the recorded tuberculous cases was 1522; 262 cases before DOTS and 1260 cases after.

This work revealed that the highest prevalence (by age) of TB was among individuals aged 15− <30 years (67.9%), and the lowest prevalence was among those of age extremes. This could be explained by the increased prevalence of smoking behavior among this active age group in our society. Moreover, poverty, malnutrition, physical, mental, and occupational stress and more exposure to infection are other contributing factors. El-Zeheiry [7], conducted a retrospective study in the

Table 2 Socio-demographic characters of the studied patients before and after the application of DOTS.

Variable		Before DOTS ($N = 262$)		After DOTS ($N = 1260$)		Total ($N = 1522$)		X^2	P
		No.	%	No.	%	No.	%		
Age (y)	<15	6	2.3	40	3.2	46	3.0	19.05	0.001*
	15−	111	42.4	396	31.4	507	33.3		
	30−	94	35.9	433	34.4	527	34.6		
	45−	41	15.6	292	23.2	333	21.9		
	60+	10	3.8	99	7.9	109	7.2		
Gender	Male	226	86.3	995	79.0	1221	80.2	7.27	0.007*
	Female	36	13.7	265	21.0	301	19.8		
Residence	Urban	200	76.3	1163	92.3	1363	89.6	59.1	<0.001*
	Rural	62	23.7	97	7.7	159	10.4		

Table 3 Site, smear and culture results among the studied patients before and after the application of DOTS.

Variable		Before DOTS (N = 262)		After DOTS (N = 1260)		Total (N = 1522)		X^2	P
		No.	%	No.	%	No.	%		
Site of TB	Pulmonary	247	94.3	1070	84.9	1317	86.5	16.3	<0.001*
	Extra pulmonary	15	5.7	190	15.1	205	13.5		
Sputum smear at diagnosis	+ve	230	87.8	893	70.9	1123	73.8	32.08	<0.001*
	−ve	32	12.2	367	29.1	399	26.2		
		(N = 230)		(N = 893)		(N = 1123)			
Sputum smear at 2nd m[†]	+ve	49	21.3	178	19.9	227	20.2	63.3	<0.001*
	−ve	89	38.7	563	63.0	652	58.1		
	Not done	92	40.0	19.9	152	244	21.7		
Sputum smear at 3rd m[†]	+ve	23	10.0	94	10.5	117	10.4	76.6	<0.001*
	−ve	57	24.8	491	55.0	548	48.8		
	Not done	150	65.2	308	34.5	458	40.8		
Sputum smear at 5th m[†]	+ve	14	6.1	58	6.5	72	6.4	162.4	<0.001*
	−ve	40	17.4	562	62.9	602	53.6		
	Dropouts	116	76.5	273	30.6	449	40.0		
Sputum smear at end treatment[†]	+ve	7	3.0	32	3.6	39	3.5	67.02	<0.001*
	−ve	58	25.2	488	54.6	546	48.6		
	Dropouts	165	71.7	373	41.8	538	47.9		
Culture results	+ve	0	0.0	6	0.5	6	0.4	FET = 8.83	0.009*
	−ve	0	0.0	30	2.4	30	2.0		
	Not done	262	100.	1224	97.1	1486	97.6		

[†] Among the smear positive cases at diagnosis.

Table 4 Type of patient and treatment outcome among the studied sample before and after the application of DOTS.

Variable		Before DOTS (N = 262)		After DOTS (N = 1260)		Total (N=1522)		Z test	P
		No.	%	No.	%	No.	%		
Type of patients	New	182	69.5	970	77.0	1152	75.7	2.58	<0.001*
	Relapse	52	19.8	50	4.0	102	6.7	9.5	<0.001*
	Failure	14	5.3	41	3.3	55	3.6	1.65	0.09
	Defaulter	13	5.0	73	5.8	86	5.7	0.53	0.59
	Transfer	0	0.0	54	4.3	54	3.6	3.41	<0.001*
	Others[‡]	1	0.4	72	5.7	73	4.8	3.68	<0.001*
Treatment outcome	Cure[§]	51	19.5	614	48.7	665	43.7	8.7	<0.001*
	Complete	36	13.7	369	29.3	405	26.6	5.2	<0.001*
	Fail	17	6.5	74	5.9	91	6.0	0.38	0.7
	Death	16	6.1	40	3.2	56	3.7	2.3	0.02*
	Default	91	34.7	95	7.5	186	12.2	12.2	<0.001*
	Transfer out	51	19.5	68	5.4	119	7.8	7.72	<0.001*

[‡] The other groups include: chronic cases, patients who are sputum positive at the end of a re-treatment regimen.
[§] For smear positive cases.

Dakahlia governorate, Egypt to review the TB situation, he found that tuberculosis was common among the middle aged group from 15− <30 years. Similar results were drawn in the El-Minia governorate (1997–2010) where the highest prevalence of TB occurred among the age group 15− <30 years (30.92%), and the lowest prevalence occurred in extremes of age [9]. In the present study, tuberculosis was common among men (82.2%) than women (10.4%). This could be explained by the fact that males are more active and are exposed to stress more than females. Also, many females may not seek medical advice due to factors related to illiteracy, cultural and traditional attitudes which may neglect the females' health status. Higher tuberculosis notification rates among men may partly indicate differences in exposure due to more frequent social contacts, risk of infection and progression from infection to disease caused by gender differences in association with other risk factors for tuberculosis such as alcohol abuse and smoking which are associated with pulmonary tuberculosis. Similar

Table 5 Tuberculosis indices before and after the application of DOTS.

Indices		Before DOTS ($N = 262$)		After DOTS ($N = 1260$)		St. "t"	P
		Mean	±SD	Mean	±SD		
1	Incidence rate: new cases	19.6	1.56	12.12	5.16	1.99	0.066
2	Incidence rate: new and relapse cases	25.15	0.21	12.75	5.43	3.143	0.007*
3	Incidence rate: all cases	28.19	1.7	15.81	7.68	2.214	0.043*
4	Incidence rate new smear positive pulmonary TB cases.	5.29	1.75	2.2	0.87	4.31	0.001*
5	New pulmonary TB cases with no smear result	10.55	3.52	25.26	6.92	2.9	0.011*
6	New adult smear positive cases	66.98	0.83	75.62	5.94	2.0	0.064
7	Retreatment TB cases.	22.76	6.04	5.62	2.92	7.07	0.001*
8	New extrapulmonary TB cases	5.36	0.41	14.63	6.43	1.98	0.066
9	New TB cases with no smear conversion result	57.1	11.95	46.25	19.38	0.76	0.459
10	Sputum conversion rate at the end of the initial phase of treatment.	42.9	11.95	53.75	19.38	0.76	0.459
11	Cure rate.	27.96	1.94	75.73	11.19	5.87	0.001*
12	Treatment completion rate	14.2	4.99	6.95	4.96	1.94	0.071
13	Treatment success rate	42.15	3.04	82.66	8.0	6.92	0.001*
14	Death rate	3.9	0.14	2.49	2.37	0.819	0.426
15	Treatment failure rate	3.87	1.69	6.68	3.3	1.16	0.265
16	Default rate	26.0	0.95	4.27	3.56	8.37	0.001*
17	Transfer out rate	24.1	3.64	3.91	4.12	6.55	0.001*
18	Retreatment failure rate (chronic TB rate)	88.22	4.55	45.71	17.78	3.28	0.005*

results were obtained by Floyd et al. [8], they found that male cases were 80.2% and female cases were 19.8%.

Urban cases (89.6%) were higher than rural cases (10.4%). Increased tuberculous cases in urban areas could be explained by what is reported by Atun et al. [4] who conducted a study about costs and outcomes of tuberculosis in the Russian Federation, they found that urban cases (80.8%) were significantly higher than rural cases (19.2%). They explained this result by demographic changes like increasing life expectancy, population growth, and deterioration of living conditions in urban areas like overcrowding and epidemiological factors like HIV epidemics. Also it may be due to the shift of people from rural to urban areas.

In contrast, [10] carried out a retrospective study at the Benha chest hospital over the period from 2002–2006, she stated that rural cases (76.2%) were significantly higher in comparison with urban cases (23.8%). [1], conducted a similar study in the Menoufia governorate (1992–2008), he concluded that rural cases (80.05%) were also significantly higher than urban cases (19.95%) during all years of the study. Similar findings have been reported by George [9] in the El-Minia governorate. Increased tuberculous cases in rural areas could be explained by poverty and bad social conditions and milk sanitation, also agricultural workers may acquire occupational infection by bovine bacilli from the infected animals. Moreover, it may be due to better notification of rural cases due to improved access to health care through decentralization of the services and improved patient follow up with the introduction of DOTS [15].

The current study revealed that infection among younger ages (15− and 30−) decreased significantly (42.4% and 35.9% before DOTS and 31.4% and 34.4% after DOTS respectively). The percentage of infected males was lower after DOTS than before (79% and 86.3% respectively). Infection among rural residents also became lower after DOTS than before (7.7% and 23.7% respectively) (Table 2). These findings reflect the changes that occurred in the socio demographic characters among patients, where the proportion of the younger age group decreased, males became less infected and improvement in the health services in rural areas led to a reduction in the percentage of the affected rural individuals.

In the present study there was a significant increase in extra pulmonary cases (from 5.7% to 15.1%) with a significant decrease in pulmonary cases (from 94.3% to 84.9%) before and after DOTS respectively (Table 3). This indicates more control of the pulmonary cases. Moreover, the increase in the extra pulmonary cases may be a false increase explained by more availability of diagnostic facilities such as specified X-rays or biopsy procedures which are necessary to detect extra pulmonary tuberculosis. Increased life expectancy which may be associated with reactivation of a latent tuberculous lesion from pulmonary sites and more physical contact with infected animals may also be implicated.

This work reported that the sputum conversion rate increased after DOTS at the end of the second month, the third month, fifth month and at the end of the treatment (Table 3). This reflects more treatment success that is due to new regimens of treatment with Rifampicin for six months, direct observation of cases under treatment and good follow up of patients. These results agree with Abdelghany [1], George [9] and Elwany [5]. The increase in the conversion rate in this study and all the mentioned studies means high efficacy of applying DOTS in chest hospitals and dispensaries. There is also an increase in the number of cases examined for their sputum.

As diagnosis of tuberculous cases depends mainly on direct smear examination of sputum by Z.N. staining, the role of culture in diagnosis of cases was limited. As shown in this study the number of cases examined by culture technique all over the years was only 36 (2.4%) (Table 3). Similar findings have been obtained by Abdelghany [1] and George [9]. Lack ofculture and sensitivity test use at the studied chest units may be due to that the indications of culture in DOTS include only; failure of re-treatment cases, seriously ill cases, extra pulmon-

ary cases, smear negative cases, childhood TB and HIV-TB, for multidrug resistant TB (MDR TB), not for new smear positive cases [16].

The comparison between the type of patient based on previous history of treatment before and after DOTS showed a statistically significant increase in the new cases (Table 4). Increased percentage of new cases after DOTS indicates the efficacy of diagnosis and early detection of tuberculosis. Also, it was found that Failure cases decreased after DOTS, this result denotes the efficacy of applying DOTS, efficacy of treatment and attendance of patients to take their treatment regularly.

This study revealed that the most common type of patients were new cases, which coincide with Hindi [10], Abdel-Rahmman [2], Abdelghany [1] and El-Zeheiry [7] who found that new cases represented the highest percentage of cases attended for treatment.

This study showed a significant improvement in all parameters of treatment outcome (expect for treatment failure) after DOTS, which means a good impact of applying DOTS in the chest hospitals and dispensaries. There was a marked decrease in the percentage of defaulters which constitutes a great problem during tuberculosis treatment. Treatment failure may be due to poor compliance of the patient or to practitioner error, e.g. in cases where inadequate regimens and or shortened periods of treatment are prescribed. Drug resistance may also be implicated. Unsuccessful treatment may result from irregularity in taking treatment and loss of follow up, which may be due to patients being transferred to another unit. Moreover, many patients stop treatment as soon as they feel better.

The current research declared that the mean values of incidence rates (new and relapse cases, all cases and new smear positive pulmonary TB cases) of TB were significantly ($P < 0.05$) decreased after the application of DOTS. Also, the cure rate and treatment success rate significantly increased ($P = 0.001$), while retreatment TB cases rate, default rate, transfer out rate and retreatment failure rate significantly decreased ($P < 0.05$). Finally new pulmonary TB cases with no smear result significantly ($P < 0.05$) increased after DOTS (Table 5). Increased coverage by short course chemotherapy, improved access to care through decentralization of the service and improved patient follow-up with the introduction of DOTS was observed that most likely played a significant role in improving the treatment outcomes.

Limitation of the study

Although this success of DOTS was seen there are points of weakness in the Port Said governorate Chest hospital; the high percentage of sputum negative cases (26.2%) may be false due to the decrease in the facilities of diagnosis in the governorate hospitals. 7.8% of tuberculous cases were transferred out, we have no idea about the outcome of these groups. Fewer culture results were registered about TB cases.

Conclusion

The introduction of DOTS in the Port Said governorate has led to a significant increase in treatment success (82.7%) (Near WHO target "85%"), and a decrease in default and failure rates.

Recommendations

Poor patient knowledge regarding tuberculosis may be a significant predictor of treatment failure, so strengthening health education in the DOTS strategy is therefore recommended. Patients with tuberculosis need more and more social and psychological support to decrease defaulters and treatment failure. A special registration system for the transfer out cases using a computer system with their national numbers is needed to trace the outcome of these cases.

Conflict of interest

None declared.

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